Patent
Attorney's Docket No. 032751-061

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	)	
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MEHTALI et al	)	Group Art Unit: Unassigned
	)	
Application No.: To Be Assigned	)	Examiner: Unassigned
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Filed: Herewith	)	
	)	
For: VIRAL VECTORS AND LINE FOR GENE THERAPY	)	
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PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination on the merits, please amend the above-identified application as follows:

In The Claims:

Please cancel claim 1, without prejudice or disclaimer to the subject matter disclosed therein.

Please add the following new claims 39-61:

--39. (New) A viral vector comprising an expression unit containing one or more viral genes, said expression unit being functional in a complementation cell and nonfunctional in a host cell, and comprising one or more heterologous regulator sequences.--

--40. (New) The viral vector according to claim 39, wherein said expression unit comprises one or more regulatory sequences which activate the expression of said viral gene in the presence of an inducer and/or to inhibit the expression of said viral gene in the presence of a repressor.--

--41. (New) The viral vector of claim 39, wherein said regulator sequence can act at the level of transcription, elongation, transport or stability of the messenger RNAs or translation.--

--42. (New) The viral vector of claim 41, wherein said regulator sequence is placed in the promoter of said unit.--

--43. (New) The viral vector of claim 42, wherein said regulator sequence is placed upstream of the TATA box.--

--44. (New) The viral vector of claim 39, wherein said expression unit comprises one or more regulatory sequences selected from the group consisting of TAR, RRE, GRE, PRE, ERE and Gal4 UAS sequences and the regulatory sequences of the metallothionein gene and of the bacterial tryptophans lactose and tetracycline operons.--

--45. (New) The viral vector of claim 44, wherein said expression unit comprises one or more regulatory sequences from the tetracycline operon, placed upstream of the

TATA box of said promoter, to give a promoter which is activated by an inducer or the tetracycline transactivator (tTA) type and repressible by tetracycline.--

--46. (New) The viral vector of claim 44, wherein said expression unit comprises one or more regulatory sequences from the tetracycline operon, placed downstream of the TATA box of said promoter, to give a promoter which is repressible by the tetracycline repressor (TetR).--

--47. (New) The viral vector of claim 39, wherein said viral genes are from a virus selected from the herpesvirus, cytomegalovirus, AAV (adeno-associated virus), and poxvirus.--

--48. (New) The viral vector of claim 47, wherein said viral vector is defective for replication.--

--49. (New) The viral vector of claim 39, wherein said viral vector comprises an exogenous nucleotide sequence placed under the control of the elements needed for its expression in the host cell.--

--50. (New) The viral vector of claim 39, wherein the exogenous nucleotide sequence is selected from the genes coding for a cytokine, a cell or nuclear receptor, a ligand, a coagulation factor, the CFTR protein, insulin, dystrophin, a growth hormone, an

enzyme, an enzyme inhibitor, a polypeptide having an antitumor effect, a polypeptide capable of inhibiting a bacterial, parasitic or viral infection, an antibody, a toxin, an immunotoxin and a marker.--

--51. (New) An infectious viral particle comprising a viral vector according to claim 39.--

--52. (New) A eukaryotic host cell comprising a viral vector according to claim 39.--

--53. (New) A eukaryotic host cell comprising an infectious viral particle according to claim 51.--

--54. (New) A complementation cell which complements an viral vector function, comprising an inducer and/or a repressor.--

--55. (New) The complementation cell of claim 54 further comprising a DNA fragment coding for an inducer and/or a repressor.--

--56. (New) The complementation cell of claim 54 derived from cell line 293.--

--57. (New) The complementation cell of claim 54, wherein the titer of viral particles produced by said complementation cell is greater than 5 x 10^8 pfu (plaque forming units)/ml.--

--58. (New) A method for preparing a infectious viral particle comprising a viral vector according to claim 39, wherein said method comprises:

(i) introducing a viral vector according to claim 39 into a complementation cell which complements *in trans* said viral vector, to obtain a transfected complementation cell;

(ii) culturing said transfected complementation cell under suitable conditions to permit the expression of the viral genes and the production of said infectious viral particle; and

(iii) recovering said infectious viral particle in the cell culture.--

--59. (New) A composition comprising the viral vector of claim 39, an infectious viral particle comprising a viral vector according to claim 39, a eukaryotic host cell comprising a viral vector according to claim 39, or a complementation cell which complements an viral vector function, comprising an inducer and/or a repressor, in combination with a suitable carrier.--

--60. (New) A method of therapeutically or prophylactically treating an animal in need of gene therapy, wherein said method comprises administering to an animal in need thereof a therapeutically or prophylactically effective amount of the viral vector of claim

39, an infectious viral particle comprising a viral vector according to claim 39, a eukaryotic host cell comprising a viral vector according to claim 39, a complementation cell which complements an viral vector function, comprising an inducer and/or a repressor, or a composition comprising any of the above.--

--61. (New) The method of therapeutically or prophylactically treating an animal in need of gene therapy of claim 60, wherein said method further comprises administering to said animal a repressor.--

REMARKS

Entry of the foregoing and favorable consideration of the above-identified application, in light of the following remarks, is respectfully requested. By the present amendment, claims 1-38 have been canceled and new claims 39-61 have been added. New claims 39-61 claim the same subject matter as original claims 1-38. Therefore, no new matter has been added by the present amendment.

Favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is earnestly solicited.

In the event that there are any questions relating to this application, the Examiner is invited to telephone the undersigned so that prosecution of the subject application may be expedited.

Respectfully submitted,

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